

REMARKS

This Amendment is responsive to the Office Action mailed June 5, 2008. With this Amendment, claims 1-9, 16, and 17 are withdrawn, and claim 11 is amended. Claims 1-9 and 11-18 are pending.

Support for the amendment can be found throughout the specification and claims as filed, including, e.g., at page 9, lines 2-5 and page 11, lines 5-13.

Oath/Declaration

The Office Action objects to the Declaration because the Declaration allegedly lists an incorrect title. Specifically, the Office Action asserts that the Declaration is defective because it lists the title of the invention as "Chromoprotein."

In response, Applicants submit that the Declaration is not defective. Although the title of the related PCT application is "Pigment Protein," the Declaration and the U.S. National Stage Application as filed list "Chromoprotein" as the title because "Chromoprotein" is a more exact translation of the original Japanese title of the invention. Applicants further submit that in a telephone call with Applicants' representative on July 17, 2008, the Examiner indicated that the objection to the declaration would be withdrawn.

Therefore, Applicants submit that a new Declaration is unnecessary and respectfully request the Examiner to withdraw the objection.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejects claims 11, 14, 15, and 18 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and as allegedly claiming subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Action alleges that the specification does not provide a disclosure of any particular structure to function/activity relationship in any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one to twenty amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1.

In response, Applicants submit that the claimed subject matter is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Furthermore, and while not acquiescing to the propriety of any of the assertions made in the rejection of the claims under 35 U.S.C. § 112 (written description), Applicants respectfully submit that the amendment addresses the instant rejection and respectfully request withdrawal of the same.

In particular, Applicants submit that the specification fully describes the claimed subject matter. For example, in addition to the disclosure of SEQ ID NO: 1, the instant specification discloses the complete nucleotide sequences encoding several fluorescent proteins including SEQ ID NOs: 12, 14, 16, 18, 20, and 22. Furthermore, the specification describes methods for introducing a desired mutation into nucleotide sequences (see page 12, first full paragraph), and one of ordinary skill in the art would know how such mutations correspond to protein structure.

Moreover, the specification provides guidance with regard to specific amino acid mutations and their impact on the corresponding protein's function, i.e. the protein's light absorbing and/or light emitting characteristics. In addition, the specification describes properties associated with the disclosed protein structures, for example, absorption maxima, molar absorption coefficient, pH stability, and fluorescent spectra (see, e.g., page 5, line 7 through page 7, line 6; page 7, lines 11-15; and Figures 1-12). Thus, the specification provides written description support of the disclosed and claimed genus, including a sufficient number of representative species of the genus and sufficient recitation of physical, structural, chemical, and functional properties of the disclosed and claimed subject matter.

Applicants further submit that the instant claim as amended recites an isolated DNA of either one of the following:

- (a) DNA encoding the amino acid sequence shown in SEQ ID NO: 1, or
- (b) DNA encoding the amino acid sequence shown in SEQ ID NO: 1, which comprises a deletion, substitution and/or addition of one to ten amino acids, and has light-absorbing properties. As such the instant claims encompass variants which are greater than 95% homologous to SEQ ID NO: 1, and which have a particular function, i.e. which have light-absorbing properties. In view of the above, Applicants submit that the claimed invention is more than sufficiently supported by the written description provided in the instant disclosure.

Based at least on the foregoing, Applicants submit that the claimed subject matter was described in the specification in such a way as to convey to those skilled in the art that Applicants were in possession of the disclosed and claimed invention at the time of filing. Therefore, Applicants respectfully request reconsideration and withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph.

The Office Action also rejects claims 11, 14, 15, and 18 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Action alleges that the specification, while being enabling for an isolated nucleic acid sequence comprising SEQ ID NO: 2 which encodes a chromoprotein from *Cnidopus japonicus*, and for one to nine amino acid substitutions of SEQ ID NO: 1, does not reasonably provide enablement for any DNA of either one of the following: (a) DNA encoding the amino acid sequence shown in SEQ ID NO: 1 or (b) any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one to twenty amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and having light-absorbing properties. In particular, the Action alleges the claims do not place any structural limits on “any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one to twenty amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1.” Furthermore, the Office Action alleges that the specification does not establish (A) a rational and predictable scheme for modifying any nucleic acid with an expectation of obtaining the desired biological function in the encoded polypeptide, and (B) sufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

In response, Applicants submit that the specification provides sufficient guidance such that one of skill in the art could make and use the invention without undue experimentation. Furthermore, and while not acquiescing to the propriety of any of the assertions made in the rejection of the claims under 35 U.S.C. § 112 (enablement), Applicants respectfully submit that the amendment addresses the instant rejection and respectfully request withdrawal of the same. Applicants have, for example, amended claim 11 to recite “[a]n isolated DNA of either one of the following:

(a) DNA encoding the amino acid sequence shown in SEQ ID NO: 1, or
(b) DNA encoding the amino acid sequence shown in SEQ ID NO: 1, which comprises a deletion, substitution and/or addition of one to ten amino acids, and has light-absorbing properties.” Thus, the nucleic acid sequences encompassed by claim 11 would not comprise a genus of nucleic acids with no structural limits as the Office Action asserts. Indeed, the sequences encompassed by the claims include those which encode amino acid sequences with greater than 95% homology to SEQ ID NO: 1.

Applicants further submit that whether or not an Applicant’s invention is enabled has been determined by the courts to involve several factors including the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicants submit that the specification, in combination with the prior art, provides sufficient guidance with respect to the encompassed sequences, such that one of ordinary skill in the art could make and use the invention without undue experimentation. Applicants further assert that the skill level of one of ordinary skill in this particular art is high, and that one of ordinary skill in the art would know, based on the instant disclosure and the prior art, those amino acid sequences and even those amino acids residues involved in the protein’s light-absorption properties, and therefore, which amino acids could be deleted, substituted, and/or added.

Applicants wish to emphasize that the disclosure provides the detailed sequence structure for exemplary proteins and their corresponding nucleic acids. Indeed, the specification indicates particular amino acids, which can be modified to alter the proteins' light-absorbing and/or light-emitting properties (see, e.g. page 9, line 19 through page 10, line 18; Examples 3-5 on pages 23-26; and Figures 1-12). Furthermore, one of ordinary skill in the art would be familiar with methods of making and/or isolating mutants and variants of the disclosed and claimed subject matter based on the guidance provided by the specification and the state of the art. In this regard the claimed invention is also enabled for at least the reasons set forth in Applicants' response to the rejection of the claims under 35 U.S.C. § 112, first paragraph (written description), e.g., the specification describes methods for introducing a desired mutation into nucleotide sequences (see page 12, lines 2-9), and one of ordinary skill in the art would know how such mutations correspond to protein structure.

Based on at least the above, Applicants submit that the instant disclosure provides clear and sufficient guidance such that the claimed invention is enabled. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejections under the enablement requirement of 35 U.S.C. §112, first paragraph.

Claim Rejections – 35 U.S.C. §102(b)

The Office Action rejects claims 11, 14, 15 and 18 under 35 U.S.C. § 102(b) as allegedly anticipated by Lukyanov et al. (U.S. Patent No. 6,969,597; hereinafter LUKYANOV). In particular, the Office Action alleges that LUKYANOV teaches a polynucleotide of SEQ ID NO: 9, which anticipates the rejected claims.

In response, Applicants submit that SEQ ID NO: 9 disclosed in LUKYANOV encodes a polypeptide with only 62.5 % sequence identity to SEQ ID NO: 1 and which has only 48.2%

sequence identity to SEQ ID NO: 2 of the instant invention, and as such does not anticipate the claimed invention.

Applicants respectfully request withdrawal of the rejection.

Allowable Subject Matter

Applicants thank the Examiner for the indication of allowable subject matter.

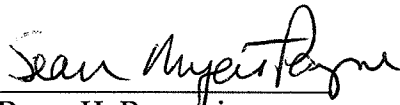
CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow all the pending claims.

No additional fee is believed due at this time. If, however, any additional fee is necessary to ensure consideration of the submitted materials, the Patent and Trademark Office is hereby authorized to charge the same to Deposit Account No. 19-0089.

Any comments or questions concerning this application can be directed to the undersigned at the telephone number given below.

Respectfully submitted,
Atsushi MIYAWAKI et al.

A handwritten signature in dark ink, appearing to read "Sean Myer Payne", is written over a horizontal line.

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